



CANNON BUILDING
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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, October 18, 2017 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	January 17, 2018

MEMBERS PRESENT

Hooshang Shanehsaz, R.Ph., Professional Member, President
Bonnie Wallner, R.Ph., Professional Member
Susan Esposito, R.Ph., Professional Member,
Nicholas Juliano, PharmD, Professional Member
Jay Galloway, Public Member
Gayle MacAfee, Public Member

MEMBERS ABSENT

Tejal Patel, PharmD, Professional Member, Vice President
Kimberly Robbins, R.Ph., Professional Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

David Mangler, Director
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Timothy Dillon
Madeline Byrne
Ann Marie Mongeluzo
Suzanne Rabb-Long
Lisa LeGette
Izetta Henry
Archana Pariehl
Jessica Wearden
Jen Rabley
Steve Shipper

CALL TO ORDER

Mr. Shanehsaz called the meeting to order at 9:30 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Esposito and seconded by Ms. Wallner to approve the meeting minutes for August 26, 2017 with changes. The motion carried.

A motion was made by Ms. Esposito and seconded by Ms. MacAfee to table the September 20, 2017 meeting minutes. The motion unanimously carried.

UNFINISHED BUSINESS

Statutory and Regulatory Discussion

Review of 24 Del. C. Sec. 2533 (a) and Regulation 3.6 "Closing of Pharmacy When Pharmacist not Present" – Ms. Kelly will review further to see if this requires a statutory or regulatory change and provide the Board more information in November.

Re-review of tabled application – UPS Supply Chain Solutions, Inc. (NJ), a motion was made by Ms. Esposito and seconded by Mr. Galloway to approve the application. The motion unanimously carried.

Final Denial of Application – Tri-Coast Pharmacy, Inc. (FL), a motion was made by Ms. Esposito and seconded by Mr. Galloway to final deny the application due to no response for the request of proposal to deny hearing. The motion unanimously carried.

PRESIDENT'S REPORT

Mr. Shanehsaz stated that he was on a call with Substance Abuse and Mental Health Services Administration (SAMHSA) which announced that the State of Delaware and CVS has reached an agreement to offer Naloxone to patients through a standing order from the Division of Public Health. The patient must provide proof of training and sign an acknowledgment form at the pharmacy. The standing order allows the following types of administration: Narcan Nasal Spray, Evzio and cartridges for the atomizer. Refills are permitted; however, paperwork must be completed each time by the patient.

Mr. Shanehsaz also reported that SAMHSA stated that there was an FDA Warning regarding combining benzo opioids. Information is to be added to Opioids, Benzodiazepine and buprenorphine and methadone drug labels.

Hazardous drugs handling in health care settings or USP800 issued an extension to be in compliance is now December 1, 2019.

Mr. Shanehsaz stated that the city of Chicago is currently working on regulations limiting pharmacist processing of patient prescriptions to no more than 10 patients per hour, and for guaranteed meal and break times. If anyone works more than 8 hours continuously they must post the name of that pharmacist and technicians for the public to see. This would help to ensure patient safety. A study completed resulted in 52% of patients receiving medications were not properly consulted or not consulted at all.

Mr. Shanehsaz stated that www.helpisherede.com provides valuable resources to those in need. As pharmacists we should educate the public on this resource whenever possible.

NEW BUSINESS

Mr. Shanehsaz read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0005117	Amanda Rae Lehmann
A1-0005118	Hong A. Kim
A1-0005119	Jordyn C. Loy
A1-0005120	Alison E. Bukowitz
A1-0005121	Tam Bao Nguyen
A1-0005122	Shannon M. Adams
A1-0005123	Ejike Chukwukere
A1-0005124	Khoa Anh Bui
A1-0005125	Kinjal Mehul Desai
A1-0005126	Parth Jagdishbhai Patel
A1-0005127	Ikenna Anyanwu

A1-0005128 Elena Stambone
A1-0005129 Katherine Marie Lurk
A1-0005130 Alexander Scott Bimson
A1-0005131 Nguyet Anh Le
A1-0005132 Chioma Sandra Aigbedo
A1-0005133 Sara El-Baff
A1-0005134 Sean William Wolf
A1-0005135 Catherine Ronalder
A1-0005136 Maria del C. Chaar
A1-0005137 Michelle Sebok
A1-0005138 Rebecca C. Gordon
A1-0005139 Crystal R Schnur
A1-0005140 Constance L. Smith
A1-0005141 Eric V. Nguyen
A1-0005142 Jagadishkumar N. Rabadia
A1-0005143 Steven Andersen
A1-0005144 Timothy John Derosé
A1-0005145 Aaron M. Gehring

A motion was made by Ms. MacAfee and seconded by Ms. Esposito to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

A7-0002472 Todd Holden
A7-0002473 Bryce Sona Gokool

A motion was made by Ms. MacAfee and seconded by Ms. Esposito to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0002067 FLTX LLC
A9-0002068 Creative Pharmacy Solutions Central, LLC
A9-0002069 SmartScripts LLC
A9-0002070 Neff Drugs 30, LLC
A9-0002071 Pharmacy Innovations, LLC
A9-0002072 Super Saver Pharmacy #4, LLC
A9-0002073 Pharmaceutical Specialties, Inc. dba Hoyer's Pharmacy
A9-0002074 Prime Therapeutics Specialty Pharmacy LLC
A9-0002075 Avita Drugs LLC
A9-0002076 Express Veterinary Pharmacy, LLC
A9-0002077 GenX Pharmacy
A9-0002078 BAYADA Pharmacy
A9-0002079 Anchor Care Pharmacy, Inc
A9-0002080 Rite Care Pharmacy
A9-0002081 Rite Care Pharmacy V
A9-0002082 PharmaCord

A motion was made by Mr. Galloway and seconded by Ms. Wallner to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0002378 Nielsen BioSciences, Inc.
A4-0002442 Epic Pharma, LLC
A4-0002443 Emes 2 Pharmaceuticals, LLC
A4-0002445 Dendreon Pharmaceuticals LLC
A4-0002446 ALFASIGMA USA, Inc.

A4-0002447 DML Pharm Corporation
A4-0002448 Exel Inc. dba DHL Supply Chain (USA)
A4-0002449 ICU Medical Sales, Inc.
A4-0002450 RxC Acquisition Company
A4-0002451 RxC Acquisition Company

A motion was made by Mr. Galloway and seconded by Ms. Wallner to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Distributor Licensure Approval Ratifications

A2-0000149 Nationwide Medical, Inc.

A motion was made by Mr. Galloway and seconded by Ms. Wallner to approve the ratification of the Medical Gas Distributor applications. The motion unanimously carried.

Manufacturer

None

Retail Pharmacy Licensure Approval Ratification

None

Non-Retail Pharmacy Licensure Approval Ratification

None

Outsourcing Facility

None

Pharmacist-In-Charge Interviews

A motion was made by Ms. Esposito and seconded by Mr. Galloway to amend the agenda to add the following for PIC interview. PIC-Madeline Byrne, Bayhealth Ambulatory Care, Milford, DE. and PIC-Ann Marie Mongeluzo, Rite Aid #04918, Georgetown, DE. The motion unanimously carried.

Ms. Esposito conducted the Pharmacist-in-Charge interviews for the following:

PIC – Izetta Henry, Walgreens, Harrington, DE

PIC – Chintan Rana, Walgreens, Dover, DE. Chintan Rana, did not appear today for the interview process.

PIC - Madeline Byrne, Bayhealth Ambulatory Care, Milford, DE.

PIC - Ann Marie Mongeluzo, Rite Aid #04918, Georgetown, DE.

Board Review of Facility Applications

Costco Pharmacy #583 (WA) - a motion was made by Ms. Wallner and seconded by Ms. Esposito to table the application for additional information. The motion unanimously carried.

OKC Allergy Solutions, Inc. (OK) - a motion was made by Ms. MacAfee and seconded by Ms. Wallner to approve the application. The motion unanimously carried.

Board Review of Pharmacist Applications

None

Continuing Education Review

None

Pharmacist and Pharmacy - Discussion/Action Items

None

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz, Bonnie Wallner and Gayle MacAfee

No Report

Continuing Education – Bonnie Wallner, Tejal Patel

No Report

Consumer Affairs – Jay Galloway, Gayle MacAfee

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

Mr. Shanehsaz attended the Controlled Substance Advisory Committee meeting and discussed the Board of Pharmacy's request that statute changes occur in which hypodermic syringes no longer require a prescription and that they be made available over the counter with provisions to require records to be kept for dispensing of these syringes. The committee agreed to review and update the statute and regulation.

Ms. Esposito attended the Pennsylvania Society of Health-Systems Pharmacists (PSHP) meeting and there is going to be a "Preventing Drug Diversion" meeting April 8, 2018 in Harrisburg, PA which will be 8 hours.

Controlled Substance Liaisons –Tejal Patel, Hooshang Shanehsaz:

No Report

INSPECTION and PMP REPORT - Michelle McCreary

Ms. McCreary reported the following inspection activities

- 3 – Remodel Inspections
- 3 – Preconstruction Inspections
- 4 – Complaint Inspections/return Visit 1 office
- 1 – Complaint Child Services
- 1 – Complaint DE Health Services, Hospital Pharmacy
- 3 – Investigative Inspection
- 3 – Closing Pharmacy Visits
- 3 – Ongoing Division Investigation Follow up Inspections

Ms. McCreary is also attended the FDA 503A/503B meeting at the end of September with Ms. Kelly.

Mr. Mangler stated that Mr. Slavoski was attending the NASCSA conference and that the PMP is in the midst of migrating to the new Appriss platform. Notices to uploaders providing instruction to establish and account on the new platform have been sent. Notices to users explaining action items required to be completed by the users have also been sent. The target rollout date is November 7, 2017. There will be a 2 week lag in prescription data until the migration is completed at the end of November.

Mr. Mangler stated that the first Prescription Drug Action Committee (PDAC) met on September 25, 2017. There was only a very small portion of the meeting open to the public. The next meeting will be scheduled sometime during the latter part of November 2017.

Mr. Mangler also stated that the position of Executive Director for the Board of Pharmacy and Office of Controlled Substances would be posted. This position requires the individual be a licensed pharmacist in this state to qualify.

Physician Assistant Council

Mr. Shanehsaz states that he attended the council meeting. The council is currently working on collaborative care. He will continue to attend this council meets quarterly.

Request to Lift Probation

Timothy Dillon – Mr. Dillon appeared in front of the Board and presented his request. The Board reviewed the requirements of the imposed probation. A motion was made by Ms. Wallner and seconded by Ms. Esposito to lift the probation and return the license to active status. The motion unanimously carried.

BOARD CORRESPONDENCE

The following correspondence was reviewed by the members of the Board.

Safe Biologics - Alliance for Safe Biologic Medicines

NABP - Tri Regulator Collaborative Release Position Statements Addressing Electronic Health Records, Practitioner Burnout

FDA Commissioner Gottlieb on New Efforts to Encourage Compounding of Better Quality Drugs Under DQSA
DEA Drugs of Abuse 2017 Report

NABP Seeks Volunteers for the FMEDS Program Team to Develop a First Aid Protocol for Victims of Falsified Medications

NABP - Improved NABP Online Systems Coming in 2018

Mississippi Board of Pharmacy Phone Number

NABP - State and Federal Occupational Licensing Reform

Mr. Mangler addressed the roles Delaware has in this reform. Executive order 60 required the review of all Boards and any barriers to licensure that may occur. This review was completed and there were several processes, statutes and regulation to be reviewed further to possibly remove barriers to licensure. This process is on-going.

CVS to Limit Opioid Drug Prescriptions amid National Epidemic

Mr. Juliano stated that CVS is taking the initiative to protect its patients from possible drug abuse or overdose. Limiting dispensing to 7 days and monitoring new pain patients will help to assist in prevention of addiction and abuse.

OTHER BUSINESS BEFORE THE BOARD

Ms. Esposito stated that there would be a drug take back event held on the Cape May Lewes Ferry on October 28, 2017.

PUBLIC COMMENT

Mr. Shanehsaz stated that HIV Medications paid for through Medicaid have become unavailable to some patients due to new procedures implemented at Medicaid. Mr. Shanehsaz will reach out to other stakeholders for input to assist the Board in writing a letter to the insurance commissioner.

Ms. Esposito has spoken with wholesale distributors regarding shortages in medications. These shortages may increase the use of gray market medication.

NEXT SCHEDULED MEETING

The next meeting is scheduled for November 15, 2017 at 9:30 a.m., 2nd Floor Conference Room.

ADJOURNMENT

There being no other business before the Board, a motion to adjourn the meeting was made by Ms. MacAfee and seconded by Ms. Esposito at 11:35 am. The motion unanimously carried.

Respectfully submitted,



Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy